Appendix K

Proposed Maryland Patient Safety Regulations

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Preface

In 2001,the Maryland General Assembly expressed concern over patient safety in Maryland hospitals and asked the MHCC, in consultation with DHMH, to review activities and to make recommendations for improvements. The Patient Safety Coalition was started and has recommended a three-prong approach. This includes:

1) Creation of a Patient Safety Center to act as a clearinghouse and repository for de-identified, voluntarily reported patient safety information,
2) Development of systems within Maryland health care facilities to prevent adverse events and enhance patient safety, and
3) Revising the Risk Management regulations.

The following draft regulations are part of the third initiative. The purpose is two-fold:

1) To strengthen accountability of hospitals for certain events that cause death or harm to patients; and
2) To strengthen the internal reporting and evaluation systems within hospitals.

The regulations are based on recommendations from the 1999 IOM study "To Err is Human," JCAHO Accreditation Standards for Hospitals, the Department of Veterans Affairs Patient Safety program, and the National Quality Forum's Consensus Report of Serious Reportable Events.

Changes from current regulations

- Defines adverse event, near-miss, root cause analysis and action plan.
- Encourages identification and reporting of near-misses.
- Specifies type of response to serious adverse events and near-misses.
- Require notification to a patient and, when appropriate, that patient's family of an outcome of care that differs significantly from an anticipated outcome.
- Specifies reports to the Department and emphasizes confidentiality of reports.
- Provides notice to patient and family that complaints can be filed with Department.
- Generally updates language to be consistent with JCAHO.

DEFINITIONS

"ACTION PLAN" MEANS A WRITTEN DOCUMENT THAT INCLUDES

1. SPECIFIC MEASURES TO CORRECT PROBLEMS OR AREAS OF CONCERNS;
2. SPECIFIC MEASURES TO ADDRESS AREAS OF SYSTEM IMPROVEMENT;
3. TIME FRAMES FOR IMPLEMENTATION OF ANY SPECIFIC MEASURES; AND
4. TITLE OF RESONSIBLE INDIVIDUAL TO MONITOR IMPLEMENTATION AND EFFECTIVENESS.

"ADVERSE EVENT" MEANS AN UNEXPECTED OCCURRENCE RELATED TO A PERSON'S MEDICAL TREATMENT AND NOT RELATED TO THE NATURAL COURSE OF THE PERSON'S ILLNESS OR UNDERLYING DISEASE CONDITION."

"SERIOUS DISABILITY" MEANS A PHYSICAL OR MENTAL IMPAIRMENT THAT SUBSTANTIALLY LIMITS ONE OR MORE OF THE MAJOR LIFE ACTIVITIES OF AN INDIVIDUAL LASTING MORE THAN 7 DAYS OR STILL PRESENT AT TIME OF DISCHARGE.

"LEVEL 1 ADVERSE EVENT" MEANS AN ADVERSE EVENT THAT RESULTS IN DEATH OR SERIOUS DISABILITY.

"LEVEL 2 ADVERSE EVENT" MEANS AN ADVERSE EVENT THAT REQUIRES A MEDICAL INTERVENTION TO PREVENT DEATH OR SERIOUS DISABILITY.

"LEVEL 3 ADVERSE EVENT" MEANS AN ADVERSE EVENT THAT DOES NOT RESULT IN DEATH OR SERIOUS DISABILITY AND DOES NOT REQUIRE ANY MEDICAL INTERVENTION TO PREVENT DEATH OR SERIOUS DISABILITY. EXAMPLES OF LEVEL 3 ADVERSE EVENTS INCLUDE, BUT ARE NOT LIMITED TO MEDICATION ERRORS, FALLS, TREATMENT ERRORS, INFECTIONS, COMPLICATIONS, ETC. THAT DO NOT REQUIRE ANY MEDICAL INTERVENTION TO PREVENT DEATH OR SERIOUS DISABILITY, THAT ARE UNEXPECTED OCCURRENCES, AND THAT ARE NOT RELATED TO THE NATURAL COURSE OF THE PERSON'S ILLNESS OR UNDERLYING DISEASE CONDITION.

"NEAR MISS" MEANS A SITUATION THAT COULD HAVE RESULTED IN AN ADVERSE EVENT BUT DID NOT, EITHER BY CHANCE OR THROUGH TIMELY INTERVENTION. EXAMPLES OF A NEAR-MISS INCLUDE, BUT ARE NOT LIMITED TO THE POTENTIAL FOR AN EVENT LEADING TO ANY OF THE EXAMPLES LISTED FOR A LEVEL 1, LEVEL 2 OR LEVEL 3 ADVERSE EVENT.

"PATIENT SAFETY PROGRAM" MEANS AN ONGOING, PROACTIVE PROGRAM TO IDENTIFY AND EVALUATE RISKS TO PATIENT SAFETY AND TO REDUCE MEDICAL ERRORS. THIS IS ONE COMPONENT OF A HOSPITAL-WIDE RISK MANAGEMENT PROGRAM.

"ROOT CAUSE ANALYSIS" MEANS A MEDICAL REVIEW COMMITTEE (AS DEFINED UNDER HEALTH OCCUPATIONS ARTICLE SECTION 1-401 ET SEQ., ANNOTATED CODE OF MARYLAND) PROCESS FOR IDENTIFYING THE BASIC OR CONTRIBUTING CAUSAL FACTORS THAT UNDERLIE VARIATIONS IN PERFORMANCE ASSOCIATED WITH ADVERSE EVENTS OR NEAR MISSES.

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.25 PATIENT SAFETY Program.

A. General.

(1) Each hospital shall have in effect a PATIENT SAFETY program that meets the requirements of this regulation.

(2) The purpose of this regulation is to provide a SAFE environment for patients by requiring hospitals to:

(a) Identify ADVERSE EVENTS;

(b) ENCOURAGE REPORTING OF NEAR MISSES.

(c) ASSESS AND PRIORITIZE NEAR-MISSES AND ADVERSE EVENTS BASED ON LEVEL OF DISABILITY OR POTENTIAL DISABILITY TO PATIENTS;

(d) DETERMINE THE APPROPRIATE HOSPITAL RESPONSE BASED ON LEVEL OF DISABILITY OR POTENTIAL DISABILITY;

(e) CONDUCT A ROOT CAUSE ANALYSIS ON
   i. ALL LEVEL 1 EVENTS;
   ii. ALL LEVEL 2 EVENTS; AND
   iii. ANY NEAR-MISS OR OTHER ADVERSE EVENT IF WARRANTED.

(f) CONDUCT AN APPROPRIATE INVESTIGATION ON ADVERSE EVENTS AND NEAR-MISSES THAT DO NOT REQUIRE OR WARRANT A ROOT CAUSE ANALYSIS;

(g) Provide for a process by which the concerns of patients can be addressed; AND

(h) PROVIDE FOR A PROCESS TO INFORM THE PATIENT AND, WHEN APPROPRIATE, THE PATIENT'S FAMILY, WHENEVER AN OUTCOME OF CARE DIFFERS SIGNIFICANTLY FROM AN ANTICIPATED OUTCOME.

B. Duties of Hospital.

(1) The hospital shall identify an individual as PATIENT SAFETY coordinator who shall:

(a) Coordinate PATIENT SAFETY activities;

(b) FACILITATE ASSESSMENT AND DETERMINATION OF THE APPROPRIATE RESPONSE TO REPORTED NEAR MISSES AND ADVERSE EVENTS related to patient care;

(c) MONITOR ROOT CAUSE ANALYSES AND ANY ACTIONS RESULTING FROM A ROOT CAUSE ANALYSIS; AND

(d) Provide for flow of information among quality assurance, credentialing, peer review, and any PATIENT SAFETY committee.

(2) The hospital shall establish:

(a) PATIENT SAFETY education programs for all staff; and

(b) An internal staff committee structure IN ACCORDANCE WITH HEALTH OCCUPATIONS ARTICLE § 14-501 to conduct review and evaluation of PATIENT SAFETY activities in accordance with this regulation.

(3) The GOVERNING board of a hospital shall DEVELOP A PROCESS TO REVIEW THE HOSPITAL'S PATIENT SAFETY PROGRAM AND TO DETERMINE THE EFFECTIVENESS OF THE HOSPITAL'S PATIENT SAFETY PROGRAM.

(4) Before a committee can operate or review PATIENT SAFETY activities under this regulation, a hospital shall require that the committee meet the requirements for a medical review committee under Health Occupations Article, § 1-402 et seq., Annotated Code of Maryland.

C. PATIENT SAFETY Program Requirement-- NEAR MISS AND ADVERSE EVENT Reporting AND DETERMINATION OF APPROPRIATE RESPONSE.

(2) THE HOSPITAL SHALL DEVELOP AND ENCOURAGE A SUPPORTIVE ENVIRONMENT THAT PERMITS SPONTANEOUS IDENTIFICATION,

OPEN DISCUSSION, AND TIMELY AND ACCURATE REPORTING OF NEAR-MISSES AND ADVERSE EVENTS.

(3) THE HOSPITAL SHALL ESTABLISH A CLEAR AND WELL-DEFINED NEAR MISS AND ADVERSE EVENT identification and reporting process THAT SHALL

(a) ENCOURAGE REPORTING OF NEAR-MISSES AND REQUIRE REPORTING OF ADVERSE EVENTS;

(b) List and describe EXAMPLES OF ADVERSE EVENTS that shall be reported;

(c) Designate a hospital representative to whom A NEAR-MISS SHALL BE ENCOURAGED TO BE REPORTED OR ADVERSE EVENT shall be reported;

(d) Provide a time frame within which the NEAR-MISS SHALL BE ENCOURAGED TO BE REPORTED OR ADVERSE EVENT shall be reported;

(e) Require that a person employed by the hospital or appointed to the medical staff and who is aware of AN ADVERSE EVENT shall report the ADVERSE EVENT in accordance with this regulation;

(f) DEVELOP A PROCEDURE TO COORDINATE RECEIPT OF ALL ADVERSE EVENTS AND NEAR-MISSES AND TO PRIORITIZE ADVERSE EVENTS AND NEAR-MISSES BASED ON LEVEL OF DISABILITY OR POTENTIAL DISABILITY; AND

(g) DEVELOP A PROCEDURE TO ASSIGN AN APPROPRIATE RESPONSE TO LEVEL 1 AND LEVEL 2 ADVERSE EVENTS, OTHER ADVERSE EVENTS, AND NEAR-MISSES.

D.PATIENT SAFETY PROGRAM – INVESTIGATION OF LEVEL 1 AND 2 ADVERSE EVENTS AND NEAR MISSES THAT WARRANT ROOT CAUSE ANALYSES

(1) WHEN A LEVEL 1 OR 2 ADVERSE EVENT OR A NEAR-MISS THAT WARRANTS A ROOT CAUSE ANALYSES OCCURS, THE HOSPITAL SHALL:

~~a)~~(a) PROVIDE IMMEDIATE CARE TO THE PATIENT;

~~b)~~(b) IDENTIFY ANY IMMEDIATE CORRECTIVE ACTION TO PREVENT REOCCURRENCE;

~~c.~~(c) IDENTIFY AND REPORT THE EVENT IN ACCORDANCE WITH THE HOPSITAL'S REPORTING PROCESS;

~~d.~~(d) COMPLETE A ROOT CAUSE ANALYSIS WITHIN 60 DAYS OF THE TIME THAT THE HOSPITAL HAS KNOWLEDGE OF THE OCCURRENCE;

~~e.~~(e) DEVELOP AND IMPLEMENT AN ACTION PLAN TO CORRECT ANY SYSTEMS PROBLEMS;

~~f.~~(f) SHARE ANY PERTINENT INFORMATION WITH QUALITY ASSURANCE OR OTHER MEDICAL REVIEW COMMITTEES; AND

~~g.~~(g) AGGREGATE DATA TO DETERMINE PATTERNS OR TRENDS.

(2) ALL PATIENT SAFETY ACTIVITIES SHALL BE CONDUCTED BY A MEDICAL REVIEW COMMITTEE ESTABLISHED UNDER HEALTH OCCUPATIONS ARTICLE § 1-401.

E.PATIENT SAFETY PROGRAM REQUIREMENT – ROOT CAUSE ANALYSIS

(1) THE HOSPITAL SHALL APPOINT AN INTERDISCIPLINARY ROOT CAUSE ANALYSIS TEAM THAT SHALL INCLUDE:

~~a.~~(a) INDIVIDUALS WHO HAVE KNOWLEDGE OF THE EVENT OR NEAR- MISS,

~~b.~~(b) REPRESENTATIVES OF HOSPITAL LEADERSHIP; AND

(c) INDIVIDUALS WITH EXPERTISE IN THE SUBJECT MATTER OF THE EVENT.

(2) THE ROOT CAUSE ANALYSIS TEAM SHALL INTERVIEW AND PERMIT PARTICIPATION OF INDIVIDUALS WHO WERE DIRECTLY INVOLVED IN THE EVENT OR NEAR MISS AND ALLOW THE INDIVIDUAL TO PARTICIPATE IN THE ROOT CAUSE ANALYSIS PROCESS AS APPROPRIATE.

(3) THE ROOT CAUSE ANALYSIS SHALL EXAMINE THE CAUSE AND EFFECT OF THE EVENT THROUGH AN IMPARTIAL PROCESS THROUGH:

~~a.~~(a) ANALYSIS OF HUMAN AND OTHER FACTORS;

~~b.~~(b) ANALYSIS OF RELATED PROCESSES AND SYSTEMS;

~~c.~~(c) ANALYSIS OF UNDERLYING CAUSE AND EFFECT SYSTEMS THROUGH A SERIES OF WHY QUESTIONS;

~~d.~~(d) IDENTIFICATION OF RISKS AND POSSIBLE CONTRIBUTING FACTORS; AND

~~e.~~(e) DETERMINATION OF IMPROVEMENT IN PROCESSES OR SYSTEMS.

~~(3)~~(4) A ROOT CAUSE ANALYIS SHALL:

~~a.~~(a) BE INTERNALLY CONSISTENT; AND

(b) INCLUDE CONSIDERATION OF RELEVANT LITERATURE AND BEST PRACTICES.

(5) THE HOSPITAL SHALL PROVIDE FEEDBACK INCLUDING CHANGES TO HOSPITAL POLICY OR PROCEDURE RESULTING FROM THE ROOT CAUSE ANALYSIS TO HOSPITAL EMPLOYEES AND STAFF THAT WERE INVOLVED IN THE EVENT OR NEAR-MISS AND TO OTHER EMPLOYEES OR STAFF THAT WOULD BENEFIT FROM THE FEEDBACK.

F.PATIENT SAFETY PROGRAM REQUIREMENT – LEVEL 3 ADVERSE EVENT OR NEAR-MISSES THAT DO NOT WARRANT ROOT CAUSE ANALYSES

~~1.~~(1) IF THE EVENT IS NOT A LEVEL 1 OR 2 EVENT OR NEAR-MISS THAT WARRANTS A ROOT CAUSE ANALYSIS, THE HOSPITAL SHALL CONDUCT AN EVALUATION OF THE EVENT TO DETERMINE ANY PROBLEM AREA AND CORRECTIVE ACTION.

~~2.~~(2) ALL EVENTS SHALL BE AGGREGATED BY TYPE AND LEVEL TO DETERMINE ANY PATTERNS OR TRENDS.

~~3.~~(3) THE HOSPITAL IS ENCOURAGED TO EVALUATE AND TREND ALL NEAR MISSES TO DETERMINE ANY SYSTEM PROBLEMS.

~~4.~~(4) THE HOSPITAL SHALL MONITOR THE RESULTS AND EFFECTIVENESS OF ALL ACTION PLANS.

G. PATIENT SAFETY Program Requirement--Information Sharing. The PATIENT SAFETY program shall require that the quality assurance, AND OTHER MEDICAL REVIEW COMMITTEES share information AND TAKE ANY APPROPRIATE ACTION CONCERNING NEAR-MISSES AND ADVERSE EVENTS.

H. PATIENT SAFETY PROGRAM REQUIREMENT -- REPORTS TO THE DEPARTMENT

(1) A HOSPITAL SHALL REPORT ANY LEVEL 1 ADVERSE EVENT TO THE DEPARTMENT WITHIN 5 DAYS OF THE HOSPITAL'S KNOWLEDGE THAT THE EVENT OCCURRED.

(2) A HOSPITAL SHALL SUBMIT THE ROOT CAUSE ANALYSIS AND ACTION PLAN FOR THE LEVEL 1 ADVERSE EVENT TO THE DEPARTMENT WITHIN 60 DAYS OF THE OCCURRENCE.

(3) ANY ROOT CAUSE ANALYSES AND ANY OTHER MEDICAL REVIEW COMMITTEE INFORMATION SUBMITTED TO THE DEPARTMENT IS CONFIDENTIAL AND SHALL NOT BE DISCOVERABLE OR ADMISSABLE AS EVIDENCE IN ANY CIVIL ACTION AS PROVIDED UNDER HEALTH –OCCUPATIONS ARTICLE § 1-401.

(4) IF THE DEPARTMENT RECEIVES A COMPLAINT ALLEGING A LEVEL 1 ADVERSE EVENT, THE DEPARTMENT MAY ACCEPT THE ROOT CAUSE ANALYSIS AS A HOSPITAL'S INTERNAL INVESTIGATION UNDER HEALTH GENERAL 19-309(b).

I. PATIENT SAFETY Program Requirement--Documentation. Actions taken by the quality assurance and medical staff credentialing and peer review committees shall be documented in committee minutes.

J. PATIENT SAFETY Program Requirement--Patient Complaint Program.

(1) In accordance with this section, the PATIENT SAFETY program shall include a formal written program for addressing patient complaints.

(2) The hospital shall provide patients with information regarding the hospital's patient complaint program including:

(a) The name of the hospital's representative that the patient may contact if the patient wishes to make a complaint; and

(b) The hospital representative's phone number or address.

(3) The hospital's representative shall treat the COMPLAINANT with dignity and courtesy and due regard for the person's privacy.

(4) The hospital's representative shall provide the COMPLAINANT with information about the complaint including:

(a) THE hospital REPRESENTATIVE THAT the patient may contact for information regarding the complaint;

(b) The procedure for investigating the complaint;

(c) THE LENGTH OF TIME IN WHICH THE COMPLAINANT can expect a response or resolution to the complaint; AND

(d) NOTICE THAT THE PATIENT MAY CONTACT THE DEPARTMENT AT A SPECIFIED TELEPHONE NUMBER OR ADDRESS WITH ANY COMPLAINT.

(5) The hospital's representative shall document the complaint and any action taken concerning the complaint or the hospital function complained about.

K. PATIENT SAFETY PROGRAM REQUIREMENT – NOTICE TO PATIENTS AND FAMILIES OF UNANTICIPATED OUTCOMES

THE HOSPITAL SHALL INFORM THE PATIENT AND, WHEN APPROPRIATE, THE PATIENT'S FAMILY, WHENEVER AN OUTCOME OF CARE DIFFERS SIGNIFICANTLY FROM AN ANTICIPATED OUTCOME.

L.PATIENT SAFETY PROGRAM REQUIREMENT – INTERHOSPITAL NOTIFICATION OF LEVEL 1OR LEVEL 2 ADVERSE EVENTS.

(1) A HOSPITAL THAT ADMITS A PATIENT WITH A CONDITION RESULTING FROM AN ADVERSE EVENT THAT THE HOSPITAL PERCEIVES MAY BE RELATED TO CARE THAT WAS PROVIDED AT ANOTHER MARYLAND HOSPITAL SHALL NOTIFY AND PROVIDE ANY NECESSARY INFORMATION TO THE APPROPRIATE MEDICAL REVIEWCOMMITTEE AT THE HOSPITAL WHERE THE ADVERSE EVENT ALLEGEDLY OCCURRED.

(2) THE HOSPITAL WHERE THE EVENT ALLEGEDLY OCCURRED SHALL CONDUCT A ROOT CAUSE ANALYSIS AND PROVIDE NOTICE TO THE DEPARTMENT IN ACCORDANCE WITH THIS REGULATION.

(3) THE HOSPITAL WHERE THE EVENT ALLEGEDLY OCCURRED SHALL NOTIFY THE PATIENT OR THE PATIENT'S FAMILY IN ACCORDANCE WITH THIS REGULATION.

(4) COMMUNICATIONS THAT ARE MEDICAL REVIEW COMMITTEE COMMUNICATIONS AS DEFINED IN HEALTH–OCCUPATIONS ARTICLE § 1-401 SHALL BE TREATED AS CONFIDENTIAL, NON-DISCOVERABLE AND NOT ADMISSABLE AS EVIDENCE IN ANY CIVIL ACTION.

L. PATIENT SAFETY Program Requirement--Records. In accordance with these regulations, the hospital shall maintain records concerning the operation of its PATIENT SAFETY program.

M. Documentation.

(1) On or before (insert date), the hospital shall send to the Secretary a written description of its PATIENT SAFETY program which includes:

~~(a)~~a. The name of the PATIENT SAFETY coordinator;

~~(b)~~b. The board policy statement relevant PATIENT SAFETY activities;

(c) A description of the NEAR-MISS AND ADVERSE EVENT identification and reporting process;

(d) A list of EXAMPLES OF ADVERSE EVENTS that must be reported;

(e) A description of the NEAR-MISS AND ADVERSE EVENT review, PRIORITIZATION, evaluation, AND ROOT CAUSE ANALYSIS process;

(f) A DESCRIPTION OF THE PROCESS USED TO PROVIDE NOTIFICATION TO A PATIENT, AND, WHEN APPROPRIATE, TO A PATIENT'S FAMILY, WHENEVER AN OUTCOME OF CARE DIFFERS SIGNIFICANTLY FROM AN ANTICIPATED OUTCOME; AND

(g) A description of the formal written patient complaint process.

(2) The hospital shall notify the Secretary of any change in its PATIENT SAFETY program related to the description required by this section within 30 days of the effective date of the change.

N. Plan of Correction.

(1) If the Department notifies a hospital that the PATIENT SAFETY program of the hospital does not meet the requirements of this regulation, the hospital shall submit a plan indicating the steps the hospital shall take to meet the requirements of this regulation.

(2) The plan shall be sent to the Secretary within 30 days after the Department notifies the hospital that the hospital does not meet the requirements of this regulation.

O. Penalties. If a hospital fails to have in effect a PATIENT SAFETY program in accordance with these regulations, then the Secretary may impose upon the hospital the following penalties:

(1) Delicensure of the hospital; or

(2) A fine of $500 for each day that the hospital is in violation of these regulations.